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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,721	12/07/2001	Juan Saus	98,723-E1	5105

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,721

Applicant(s)

SAUS, JUAN

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14st and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 and 09 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/11/2003.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, drawn to nucleic acid, a vector and a host cell in response of 3/24/2005 is acknowledged. Applicant has further elected SEQ ID NO: 6. Applicants traverse on the basis that the search required to pursue the remaining claim sets extensively overlaps with the search required for Group I. Applicants arguments have been fully considered but are not considered to be persuasive because groups II and III are drawn to methods of treating or preventing autoimmune disorders and identifying candidate TNF promoters. This is not found to be persuasive because a search directed to a nucleotide sequence will not automatically lead to the identification of the treatment methods using the nucleotide encoded protein or to the identification of TNF inducible promoters. Therefore, the searches for each of the groups are not coextensive and would be a burden on the Office to search all of the different claims of the groups or the various sequences. The requirement is still deemed proper and is therefore made FINAL. Claims 14, 15 and 20-23 are with drawn as drawn to unelected invention. Thus, claims 1-13 and 16-19 are pending and examined.

Drawings

2. Applicants submission of drawing on 12/07/01 and 9/9/02 is acknowledged.

Information Disclosure Statement

3. IDS submitted on 3/11/2003 has been considered.

Priority

4. Applicants have not disclosed the various SEQ ID numbers in the provisional application 60/254, 649. Therefore, the priority is accorded to the filing date of the instant invention (12/7/2001).

Claim Objections

5a. Claim 1 is objected to because it recites many sequences, which were not elected by the Applicant in response to restriction requirement. Appropriate correction is required.

5b. Claims 1-7 are objected to because they claim one or more promoter sequences, although Applicant elected SEQ ID NO: 6 (complement is SEQ ID NO: 7) in response to the restriction requirement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claims 2-7 and 16-19 recite the use of one or more of the tumor necrosis-factor inducible promoters of claim 1. However, because of the restriction requirement, claim 1 encompasses only a single promoter sequence SEQ ID NO: 6 (Will also contain SEQ ID

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NO: 7 because it is the complement). Thus no constructs with one or more TNF inducible promoter sequences are encompassed. Claims 8-13 are rejected insofar as they are depended on rejected claims 2-7.

7. Claims 2-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a single tumor necrosis-factor (TNF) inducible promoter to induce gene expression, does not reasonably provide enablement for more than one TNF inducible promoters to induce expression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 2-13 are drawn to more than one TNF inducible promoters. The specification describes SEQ ID NO: 6 and its complement SEQ ID NO: 7 (see page 30, 2nd paragraph) along with the function. However, the specification does not teach how

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all one or more TNF inducible promoters will be assembled (e-g: in tandem etc.) in an expression construct and how they will regulate the expression of the gene of interest. In general promoters are known both to up regulate and down regulate gene expression. It is unclear from the disclosure how the addition of multiple TNF inducible promoters will function. The usefulness of the TNF inducible promoters is that in response to TNF various genes are regulated in a coordinated manner (see page 45, 2nd paragraph). In the instant application, there is no disclosure how having multiple promoters will affect gene expression. The problem of predicting the gene expression of the multiple promoters is extremely complex, requiring trial and error experimentation. Applicant has provided little or no guidance beyond the mere presentation of sequence data and individual promoter activities to enable one of ordinary skill in the art to generate the constructs of interest with one or more inducible promoters. Although the specification outlines art-recognized procedures for producing gene constructs for gene expression, this is not adequate guidance as to the nature of gene expression constructs containing the TNF inducible promoters that may be constructed (more than one), but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

A large quantity of experimentation would have been necessary for the skilled artisan to generate all expression constructs containing more than one TNF inducible promoters. The specification fails to provide sufficient direction/guidance regarding the properties of the various TNF inducible promoters in combination, contemplated for the use in gene expression constructs. There are no working examples, using more than

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one inducible promoter. The nature of the invention is complex, involving the generation of more than TNF inducible promoter containing expression constructs. The state of the prior art establishes the unpredictability of the promoter effects on gene expression. Finally, the breadth of the claims is large, failing to recite any functional limitations associated with the promoters. For all of these reasons, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stark et al. (U. S. Patent No. 6 127 176) disclose TNF inducible promoter. However, the TNF inducible described by Stark et al. appears not be SEQ ID NO: 6 or 7.

9. No claims are allowable.

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 06/05


JANET ANDRES
PRIMARY EXAMINER